21 CFR Ch. I (4-1-13 Edition)

§80.22

(4) Request for certification of a batch of color additive mixture.

Date
Office of Cosmetics and Colors (HFS-100), Center for Food Safety and Applied Nutri- tion, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 In accordance with the regulations promul- gated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color addi- tive mixture.
Name of mixture
(Manufacturer's trade name) Batch number
(Manufacturer's number)
Weight of batch pounds Volume of batch (If liquid) gallons
Batch manufactured by
Constituents of the mixture: 1. Color(s). (List separately each color and each lot number.)
Name of color as certified Lot number
Quantity used (in pounds) Obtained from
2. List of diluents. (List separately each diluent.)
Name of diluent
Quantity used
By volume
By weight (if liquid)
Batch mixed as follows
(Describe in detail) How stored pending certification
(State conditions of storage, with kind and

Required fee, \$___ (drawn to the order of Food and Drug Administration).

size of containers, location, etc.)

(State proposed uses)

Certification requested for use in

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

Title)
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[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979; 44 FR 22053, Apr. 13, 1979, as amended at 54 FR 24890, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

- (a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.
- (b) Held under the control of the person requesting certification until certified.
 - (c) Be labeled to show:
 - (1) The name of the color additive.
- (2) The manufacturer's batch number.
 - (3) The quantity of such batch.
- (4) The name and post-office address of the person requesting certification of such batch.
- (5) Be accompanied by any label or labeling intended to be used.

§80.31 Certification.

- (a) If the Commissioner determines, after such investigations as he considers to be necessary, that:
- (1) A request submitted in accordance with §80.21 appears to contain no untrue statement of a material fact;
- (2) Such color additive conforms to the specifications and any other conditions set forth therefor in parts 81 and 82 of this chapter.
- (3) The batch covered by such request otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by part 74, 81, and 82 of this chapter, is a certified batch.
- (b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with §80.21, or the batch of color additive covered by